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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
CELSA, BENNETT M	
ART UNIT	**PAPER NUMBER**
1639	

DATE MAILED: 02/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/763,914	STAHLER ET AL.	
	Examiner	Art Unit	
	Bennett Celsa	1639	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-36 is/are pending in the application.

4a) Of the above claim(s) 7,8 and 12-33 is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-6,9-11 and 34-36 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

Applicant's amendment dated 12/4/03 is hereby acknowledged.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Status of the Claims

Claims 1-36 are currently pending.

Claims 1-6, 9-11 and 34-36 are under consideration.

Claims 7-8 and 12-33 are withdrawn from consideration as being directed to a nonelected invention.

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-11) in Paper No. 9 Applicant's further election with traverse of nucleotides as the elected species which reads on claims 1-6 and 9-11 and 34-36 in Paper No. 9 is acknowledged

Withdrawn Objection (s) and/or Rejection (s)

Applicant's amendment has overcome the objection to the specification regarding the Abstract and the "Brief Description of the Drawings".

Applicant's amendment and arguments have overcome the new matter rejection of claims 1-6 and 9-11 and the "CIP" and oathe priority issues.

In light of applicant's amendment and newly added claims, the prior art rejections over the Dehlinger, Winkler and Fodor references have been withdrawn in lieu of the newly raised rejections below.

New Objection(s) and/or Rejection (s)

Claim Rejections - 35 USC § 102 and103

Claims 1-6, 11 and 34-36 are rejected under 35 U.S.C. 102(a,b,e) as being anticipated by Winkler et al. 5,677,195.

Winkler teaches the syntheses of polymer (e.g. peptides or oligonucleotides) substrate arrays for for use in screening studies for determination of binding affinity e.g. "for determining sample analytes" (e.g. see Winkler Abstract; col. 1, especially lines 10-20) comprising the steps of:

(a) providing a "support" comprising at least one channel (arranged on at least one surface anticipating claim 3) comprising a conduit having an inlet and an outlet for passing fluid from the inlet to the outlet (e.g. see Winkler figures 4-8, especially figures 5-7 and col. 11-12);

(b) passing liquid with building blocks (e.g. amino acids/nucleic acids) for synthesizing polymeric (e.g peptides/oligonucleotides) receptors through the channel or channels of the support body (e.g. see Winkler figures col. 10-11);

(c) site and/or time specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination (e.g. see Winkler col. 1, 13-15, 25-26 and patent claims) and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions. See e.g. Winkler col. 1, 13-15, figures, examples and patent claims. The Winkler reference method can attach the receptor species in a homogenous manner (e.g. identical species) or heterogenously (e.g. nonidentical species) thus anticipating claim 2. The Winkler reference teaches a large number of preferably paralled channels. See e.g. figure 4 and col. 11. The reference clearly teaches the syntheses of nucleic acid (and analogs) anticipating claims 5 and 6; and patent claims . The Winkler reference channels comprise a substrate that provides " a three dimensional surface area for syntheses" (e.g. see figures); contain a plurality of different polymer receptors (e.g. see col. 2; col. 3 (" In a preferred embodiment, a plurality of reaction regions on the substrate") and patent claims) anticipating claims 35 and 36. Additionally, the reference teaches that the reference substrate can exist as "capillaries" (e.g. see col. 10, especially lines 14-25) wherein the substrate is a capillary channel (anticipating claim 34) which contains a 3D reactive surface (anticipating claim 36). The Examiner's rationale that a small reference genus (e.g. of substrates) can serve to either anticipate or alternatively render obvious a species (e.g. capillaries) under 35 USC 102 or 103 is consistent with both sound legal precedent and PTO practice. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler '195 and Fodor et al. WO 92/10092 (6/92) incorporated by reference in the Winkler '195 patent reference.

Winkler teaches the syntheses of polymer (e.g. peptides or oligonucleotides) substrate arrays for for use in screening studies for determination of binding affinity e.g. "for determining sample analytes" (e.g. see Winkler Abstract; col. 1, especially lines 10-20) comprising the steps of:

(a) providing a "support" comprising at least one channel (arranged on at least one surface anticipating claim 3) comprising a conduit having an inlet and an outlet for passing fluid from the inlet to the outlet (e.g. see Winkler figures 4-8, especially figures 5-7 and col. 11-12);

(b) passing liquid with building blocks (e.g. amino acids/nucleic acids) for synthesizing polymeric (e.g peptides/oligonucleotides) receptors through the channel or channels of the support body (e.g. see Winkler figures col. 10-11);

(c) site and/or time specifically immobilizing the receptor building blocks in each case on predetermined positions in the channel or channels by illumination (e.g. see Winkler col. 1, 13-15, 25-26 and patent claims) and

(d) repeating steps (b) and (c) until the required receptors have been synthesized in each case on the predetermined positions. See e.g. Winkler col. 1, 13-15, figures, examples and patent claims. The Winkler reference method can attach the receptor species in a homogenous manner (e.g. identical species) or heterogenously (e.g. nonidentical species) thus anticipating claim 2. The Winkler reference teaches a large

number of preferably paralled channels. See e.g. figure 4 and col. 11. The reference clearly teaches the syntheses of nucleic acid (and analogs) anticipating claims 5 and 6; and patent claims . The Winkler reference channels comprise a substrate that provides " a three dimensional surface area for syntheses" (e.g. see figures); contain a plurality of different polymer receptors (e.g. see col. 2; col. 3 (" In a preferred embodiment, a plurality of reaction regions on the substrate") and patent claims) anticipating claims 35 and 36. Additionally, the reference teaches that the reference substrate can exist as "capillaries" (e.g. see col. 10, especially lines 14-25) wherein the substrate is a capillary channel (anticipating claim 34) which contains a 3D reactive surface (anticipating claim 36). The Examiner's rationale that a small reference genus (e.g. of substrates) can serve to either anticipate or alternatively render obvious a species (e.g. capillaries) under 35 USC 102 or 103 is consistent with both sound legal precedent and PTO practice. See e.g. *In re Schaumann*, 572 F.2d 312, 197 USPQ 5 (CCPA 1978); MPEP 2131.02; MPEP 2144.08

The Winkler et al. reference method differs from the presently claimed invention (e.g. claims 9 and 10) for failing to explicitly teach the use of a "programmable light source matrix" for illuminaion (present claim 9) and computer program patterning of polymeric receptors (present claim 10).

However, the Winkler et al. patent reference teaches that the Fodor method technique of WO 92/10092 (incorporated by reference) is "an elegant method ... for using a computer-controlled system to direct a VLSIPS ™ procedure (e.g. see Winkler patent at col. 1-2, especially col. 2, lines 1-10). The Fodor method employs a computer

programmable light source matrix in order to determine the patten of polymeric receptor(s)/ligand(s) binding . E.g see Fodor at pages 22-29; examples and claims.

Accordingly, the Winkler et al. patent reference provides motivation to one of ordinary skill in the art to employ the Fodor automated light strategy in order to achieve an elegant screening technique. Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time of applicant's invention to modify the Winkler patent teaching to employ the Fodor method use of a (computer) programmable light source matrix in order to determine the pattern of polymeric receptors in an elegant manner.

Claims 1-6, 9-11 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winkler '195 alone or combined with Fodor et al. WO 92/10092 (6/92) incorporated by refence in the Winkler '195 patent reference as applied to claims above, and, if necessary, further in view of Yeung et al. US Pat. No. 5,741,411 (4/98: filed 5/95).

The teaching of Winkler '195 alone and further in view of the WO 92 as described in the above rejection is hereby incorporated by reference in its entirety.

To the extent that newly presented claims 34 and 36 are directed to selection of a channel possessing a 3D reactive surface (e.g. a capillary channel) the Yeung et al. patent reference is offered as providing further motivation to one of ordinary skill in the art to utilize said 3D channels in the Winkler '195 method since Yeung et al. disclose and claim the *advantageous* use of parallel capillary (having a fluid inlet/outlet) arrays

in optical computerized screening of analytes in the DNA context (e.g. using CID/CCD). See Yeung, abstract, disclosure and particulary patent claims.

Accordingly, it would have been prima facie obvious to one of ordinary skill in the art the time of applicant's invention to utilize a capillary substrate system in the Winkler '195 method in view of the Winkler reference enumeration of a capillary among a small list of possible substrate reaction surfaces as a preferred substrate and, if necessary, further in view of the assay screening advantages in the DNA setting of utilizing such substrates as further taught by the Yeung et al. reference.

Discussion

Applicant's arguments directed to the above rejections were considered but deemed nonpersuasive for the following reasons.

Applicant argues that the Winkler reference teaching is limited to the use of " a flat surface with depression and trenches onto which the receptors are synthesized" in which the "flat surface or biochip is mounted on a support which may have channels for the delivery of reactants to the surface of the biochip for synthesis of the desired receptors". Applicant then argues that the syntheses reactions employing illumination only occur on the "two dimensional" biochip surface and thus will only create a two dimensional arrangement of different receptors for analytes, in contrast to the current invention which provides for the photoillumination reaction on a three dimensional surface, a channel in a support body, resulting in a three dimensional receptor arrangement

Applicant's argument was considered but deemed nonpersuasive for the following reasons.

Initially, it is noted that applicant's arguments regarding three dimensional synthetic surfaces of the presently claimed invention are only commensurate with newly added claims 34 and 36. Regarding the other claims, the Winkler reference clearly teaches site and/or time specific immobilizing of receptors in channel or channels containing fluid inlet/outlet by illumination within the scope of the presently claimed invention.

Secondly, it is also noted that even with respect to applicant's argument (which fails to interpret the reference teaching as a whole), the Winkler reference channel is 3D since it comprises the combination of a "flat surface or biochip ... mounted on a support which has channels which forms a rectangle possessing a 3D surface area for syntheses (e.g. on the substrate portion). See e.g. figures.

Finally, the Winkler reference clearly teaches, as a preferred embodiment, the utilization of a plurality of reaction regions on a substrate (e.g. see col. 3, especially lines 28-35), in which the substrate is preferentially a capillary channel. See e.g. col. 10, especially lines 14-25.

Turning to the Fodor reference, applicant argues that Fodor fails to teach or suggest channels in a support body e.g. for the syntheses of a large-library array using illumination.

In response to applicant's arguments against the Fodor reference individually, one cannot show nonobviousness by attacking a reference individually where the

rejection is based on a combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

Accordingly, for all of the reasons recited above, the newly raised rejections, are hereby maintained.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Further Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bennett Celsa whose telephone number is 571-272-0807. The examiner can normally be reached on 8-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew Wang can be reached on 571-273-0811. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Bennett Celsa
Primary Examiner
Art Unit 1639

BC
February 11, 2004